PUBLIC HEALTH COUNCIL

Meeting of the Public Health Council, Tuesday, July 18, 2000, 10:00 A.M., Massachusetts Department of Public Health, 250 Washington Street, Floor 2, Boston, Massachusetts. Present were: Dr. Howard K. Koh (Chairman), Mr. Manthala George Jr., Ms. Shane Kearney Masaschi, Mr. Benjamin Rubin, Mr. Albert Sherman, Ms. Janet Slemenda, and Dr. Thomas Sterne; Dr. Clifford Askinazi was absent (one vacancy). Also in attendance was Ms. Donna Levin, General Counsel.

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Chairman Koh announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance, in accordance with Massachusetts General Laws, Chapter 30A, Section 11A 1/2.

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The following members of the staff appeared before the Council to discuss and advise on matters pertaining to their particular interests: Mr. Richard Waskiewicz, Director, Food Protection Program, Division of Food & Drugs; Ms. Mayra Rodriguez-Howard, Director, Dr. Teresa E. Anderson, Research Coordination Unit Manager, Bureau of Substance Abuse Services; Mr. Paul Hunter, Director, Mr. Roy Petre, Assistant Director, Childhood Lead Poisoning Prevention Program; Dr. Paul Dreyer, Director, Division of Health Care Quality; Ms. Joyce James, Director, Determination of Need Program; and Attorneys Tracy Miller and Carl Rosenfield, Deputy General Counsels, Office of the General Counsel.

PERSONNEL ACTIONS:

In a letter dated July 10, 2000, Robert D. Wakefield, Jr., Executive Director, Lemuel Shattuck Hospital, recommended approval of the appointments and reappointments to the medical staff of Lemuel Shattuck Hospital, Jamaica Plain. Supporting documentation of the appointees' qualifications accompanied the recommendation. After consideration of the appointees' qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Executive Director of Lemuel Shattuck Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the following appointments and reappointments to the medical staff of Lemuel Shattuck Hospital be approved:

APPOINTMENTS	**SPECIALTY/STATUS:**	**MEDICAL LICENSE NO.**
Frederick Doherty, M.D.	Radiology/Consultant	34487
Sami Erbay, M.D.	Radiology/Consultant	152649
Alexander Kozlovsky, M.D.	Psychiatry/Active	155763

Jane Tsao, M.D.	Surgery/Active	77235

REAPPOINTMENTS	**SPECIALTY/STATUS:**	**MEDICAL LICENSE NO.**
Denis Derman, M.D.	Hematology/Oncology/Active	71758
Leendert Jack Faling, M.D.	Cardiology/Consultant	28703
John Harris, M.D.	Physical Medicine/Rehab Consultant	32488
Punyamurtula Kishore, M.D.	Internal Medicine/Consultant	43282
St. John Donnie McGrath, M.D.	Infectious Disease/ Active	78054
Elizabeth Oates, M.D.	Radiology/Consultant	55284
James Quirk, M.D.	Infectious Disease/Active	72941
Timothy Pace, M.D.	Infectious Disease/Active	152044

ALLIED HEALTH PROFESSIONAL REAPPOINTMENT	**STATUS:**	**MEDICAL LICENSE NO.**
Ellena Diggins, PA-C	Active	333

In a letter dated July 10, 2000, Blake Molleur, M.D., Executive Director, Western Massachusetts Hospital, Westfield, recommended approval of the reappointment of Marc A. Fisher, DPM to the consulting medical staff of Western Massachusetts Hospital. Supporting documentation of the appointee's qualifications accompanied the recommendation. After consideration of the appointee's qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Executive Director of Western Massachusetts Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the following reappointment be approved:

REAPPOINTMENT	**STATUS/SPECIALTY**	**MEDICAL LICENSE NO.**
Marc A. Fisher, DPM	Podiatrist	1588

REGULATION:

REQUEST FOR A TECHNICAL CORRECTION TO 105 CMR 590.000: STATE SANITARY CODE FOR FOOD ESTABLISHMENTS CHAPTER X:

Mr. Richard Waskiewicz, MS, Director, Food Protection Program, Division of Food and Drugs, presented the technical correction to 105 CMR 590.000 to the Council. He said in part, "…The Department of Public Health is proposing a technical correction to 105 CMR 590.000 to eliminate an

inconsistency with Massachusetts regulation 105 CMR 300.000, the Reportable Diseases and Isolation and Quarantine Requirements. The proposed change to 105 CMR 590.000 involves adopting the language of 105 CMR 300.000 in reference to the removal of an exclusion or restriction of a food employee who has been diagnosed with Hepatitis A virus. This technical change will insure consistency between these two regulations (105 CMR 300 and 105 CMR 590). It will also prevent possible confusion, which could result from employing slightly different criteria in the two regulations for determining when to allow a food employee to return to work. We request approval of this technical correction to 105 CMR 590.000, the State Sanitary Code for Food Establishments Chapter X by the Public Health Council. This correction will be incorporated into the amendments to 105 CMR 590.000, which were adopted by the Public Health Council on March 28, 2000 and which will be implemented on October 1, 2000."

After consideration, upon motion made and duly seconded, it was voted: (unanimously) to approve the **technical correction to 105 CMR 590.000: State Sanitary Code for Food Establishments Chapter X**: that a copy be attached and made a part of this record as **Exhibit Number 14,679;** that this correction be incorporated into the amendments approved by the Council on March 28, 2000; and that the March 28 amendments and today's technical correction be forwarded to the Secretary of the Commonwealth for promulgation. An implementation date of October 1, 2000 is expected.

The approved technical correction strikes out the words "symptoms cease" under 590.017 (B) and adds to number four (4) the following:

(a) the food employee is no longer febrile, or
(b) it has been at least one week since the onset of symptoms.

STAFF PRESENTATION: "TREATMENT WORKS" by Mayra Rodriguez-Howard, Director, Bureau of Substance Abuse Services

Ms. Mayra Rodriguez-Howard made introductory remarks, followed by Ms. Mary Brolin, of Health Addictions Research, Inc. and Dr. Teresa E. Anderson, Ph.D., Research Coordination Unit Manager, Bureau of Substance Abuse Services, who presented the report "Substance Abuse Treatment Outcomes and System Improvements" to the Council. The report indicates that treatment works. Excerpts from the Executive Summary follow:

- Clients in residential treatment programs significantly improved their employment status and abstinence rates while decreasing criminal involvement, use of emergency rooms and inpatient services, and psychological and social problems.

- Significant improvements in employment were seen for both women and men in residential treatment, as well as for whites, blacks, and Latinos.

- In FY 1999, clients in specialized residential programs for pregnant and post-partum women gave birth to 52 healthy babies, saving Massachusetts an estimated $66,000 per child in neonatal

intensive care unit treatment for the complications associated with Fetal Alcohol Syndrome and/or fetal drug exposure.

- Outpatient counseling improved clients' levels of abstinence and decreased their criminal involvement and psychological problems.

- Clients in methadone treatment reported significantly more employment, less crime, and fewer admissions to hospitals, emergency rooms and detoxification services.

- Nine out of ten clients in Drug and Alcohol Education services (DAE – for first offender drunk drivers) from FY 1994 did not re-enter treatment for drunk driving (either first or multiple offender programs) in the five fiscal years following treatment.

- Relapse Prevention Management for high utilizers of acute treatment services (ATS) significantly decreased ATS readmissions by 8 admissions per 100 clients per month.

- Supportive housing clients, particularly women and Latinos, increased their levels of part-time and full-time employment between admission and discharge.

Staff said, "These outcomes can be translated into improved quality of life for individuals, families and communities through improved health, social functioning, legal involvement, and employment. Moreover, these improvements lead to cost savings through lower health care and crime costs and increased productivity and earnings. Addressing substance abuse problems through prevention and treatment, therefore, supports the Massachusetts Department of Public Health's mission of 'helping people lead healthy lives in healthy communities.' Furthermore staff said, "BSAS strives to improve outcomes for clients by adapting services to meet their complex medical and social service needs. Toward this end, BSAS initiates and supports new services to fill the gaps in the continuum of care. Since 1998, the following services have been added to the continuum of care:

- Transitional support services to provide recovery support between acute treatment services and the next levels of treatment services in the continuum of care.

- Youth intervention services to bridge the gap between prevention and treatment services for youth.

- Criminal Justice Collaboratives or TEAM Programs (Teaching – Education – Awareness – Motivation) to bring together the criminal justice and substance abuse treatment systems to address the needs of high-risk individuals involved with the courts.

- Dual Diagnosis Program to reduce attrition and high service utilization by individuals with severe and persistent mental illness who also have substance abuse or dependency problems.

- Community Housing to provide supportive housing for previously homeless individuals and families in recovery

- Relapse Prevention Management to decrease relapses and increase retention in aftercare for high utilizers of acute treatment services.

- Children in Need of Services (CHINS) to provide substance abuse treatment and associated services to youth (and their families) for whom a CHINS petition has been filed."

Chairman Koh added, "…We have just heard about this continuum of care ranging from acute detoxification services to recovery homes, rehabilitation to outpatient methadone transitional support services, and all of us in public health are trying continually to refine that system, and to tailor the services to the needs of individual clients. There has been recently a lot of attention to serving the underserved populations such as young people, women and mothers, people with dual diagnosis, mental illness and substance abuse issues, and the homeless. This is the system that is continually in evolution. We are very proud to show data that this system does work; but as always, it could be improved. We need to continue to get in people who need treatment that we haven't been able to reach quite yet. What I am hoping, as Commissioner, is that this will be a first in a series of many presentations on substance abuse that is data driven, points to need, and directs us in terms of how to fill in gaps and serve people better."

NO VOTE/INFORMATION ONLY

INFORMATIONAL BRIEFINGS ON PROPOSED REGULATIONS:

INFORMATIONAL BRIEFING ON 105 CMR 533.000: FISH AND FISHERY PRODUCTS:

Mr. Richard Waskiewicz, Director, Food Protection Program, Division of Food and Drugs, Health Quality Management, presented the proposed regulations to the Council, accompanied by Attorney Tracy Miller, Deputy General Counsel, Office of the General Counsel. Staff said, "The Division of Food and Drugs is substantially revising 105 CMR 533.000: Fish and Fishery Products. Due to the extensive changes, the Division is striking the current regulations and replacing them in their entirety. The proposed revisions are of primary public health significance. They establish the standards for conditions and practices in Massachusetts' wholesale and retail seafood establishments. The proposed revisions are based on modern food protection standards embodied in Hazard Analysis Critical Control Point (HACCP) methodology, which incorporates the federal U.S. Food and Drug Administration (FDA) regulations on the same subject. In addition, the regulations adopt by reference relevant sections of the National Shellfish Sanitation Program's (NSSP) Model Ordinance. The Model Ordinance establishes the minimum requirements for the interstate shipment of shellfish. By adopting the relevant sections of the FDA regulations and the Model Ordinance, Massachusetts companies involved in seafood operations will operate under consistent state and federal regulations."

Staff further noted, "The amended 105 CMR 533.000 will incorporate by reference, the federal Food and Drug Administration's regulation 21 CFR Part 110: Current Manufacturing Practice in Manufacturing, Packing or Holding of Human Food and Part 123: Fish and Fishery Products as well as relevant sections of the NSSP's Model Ordinance. The adoptions of relevant good manufacturing practice sections accomplish several important goals. Federal regulations are frequently amended to reflect the current state-of-the-art practices in food protection. Adopting the federal standards by reference allows Massachusetts to maintain comparable standards for its seafood processors, facilitating in many cases the interstate commerce of seafood products. Most other states have adopted the federal standards, creating a level playing field for their seafood establishments. HACCP is now the primary, science-based system for ensuring food safety. The FDA has made a concerted effort, on the national level, to educate producers and train regulators in the fundamental concepts of HACCP. Massachusetts, in its position as a national leader in the harvesting and exporting of seafood products, must strive to ensure that this position is maintained. To do that, we must, at a minimum, conform to the national standards, including HACCP. Adopting the HACCP regulation will enable Massachusetts firms to continue as a leading force in the seafood industry….By adopting the relevant sections of the Model Ordinance, Massachusetts will require all shellfish dealers, whether or not they ship interstate, to meet the Model Ordinance's requirements…"

Attorney Miller informed the Council that the revised 105 CMR 533.000 will include new General Administration sections that will enable the Division of Food and Drugs to provide seafood dealers with specific requirements for licensing and approval…She said, "The new sections clearly delineate the administrative requirements and industry's responsibilities. They provide a number of options by which resolution of compliance issues can be achieved and help to ensure that industry's due process rights are protected."

In conclusion, staff said, "The proposed revisions to 105 CMR 533.000 address three major issues: (1) they incorporate the latest, science-based approaches to food safety; (2) they ensure that Massachusetts' seafood industry is in compliance with national standards; and (3) they clearly delineate the duties and responsibilities of both industry and the regulatory authority."
Public Hearings will be held in September 2000 and staff expects to return to the Council for promulgation in November 2000.

NO VOTE/INFORMATION ONLY

INFORMATIONAL BRIEFING ON 105 CMR 500.000: GOOD MANUFACTURING PRACTICES FOR FOOD:

Mr. Richard Waskiewicz, Director, Food Protection Program, Division of Food and Drugs, presented proposed regulations 105 CMR 500.000 to the Council. He noted the following: "The Department proposes to add a section to 105 CMR 500.000 to allow for wholesale operations in residential kitchens that meet the overall requirements of the regulation. The regulations propose to allow only the production and sale of non-potentially hazardous foods. These foods include baked goods, candies, jams and jellies. Foods in hermetically (heat) sealed containers, dairy products, foods that require

acidification for the control of harmful microorganisms and foods containing meat and poultry will not be allowed." Public hearings on the amendments will be held in August 2000.

NO VOTE/INFORMATION ONLY

INFORMATIONAL BRIEFING ON 105 CMR 595.000: LICENSURE OF VENDING MACHINE OPERATORS; AND 105 CMR 550.000: BAKERIES AND BAKERY PRODUCTS:

Mr. Richard Waskiewicz, Director, Food Protection Program, Division of Food and Drugs, presented the proposed regulations to the Council, accompanied by Attorney Tracy Miller, Deputy General Counsel, Office of the General Counsel. Staff indicated that at the March 28, 2000 Public Health Council Meeting, the Council voted to approve final promulgation of 105 CMR 590.000, State Sanitary Code for Food Establishments, Chapter X. These regulations incorporate the regulation and enforcement of retail bakeries and bakery products at 105 CMR 550.000 and vending machines at 105 CMR 595.000. 105 CMR 590.000 will be filed with the Secretary of State and become effective on October 1, 2000. All relevant aspects of 105 CMR 550.000 and 105 CMR 595.000, as they relate to retail bakeries and vending machines, respectively, are incorporated into 105 CMR 590.000. Therefore, upon implementation of 105 CMR 590.000, 105 CMR 550.000 and 105 CMR 595.000 should be rescinded in their entirety to avoid any conflicts or confusion. Public hearings will be held in August 2000."

NO VOTE/INFORMATION ONLY

INFORMATIONAL BRIEFING ON PROPOSED AMENDMENTS TO DETERMINATION OF NEED REGULATIONS 105 CMR 100.000 GOVERNING MANDATORY TERMS AND CONDITIONS:

Staff noted that they plan on holding a public hearing on the proposed amendments to Determination of Need Regulations 105 CMR 100.551, Mandatory Terms and Conditions. The first proposed amendment extends to January 1, 2003, the authorization period for determinations for any convalescent, nursing and rest home projects, if made under M.G.L.c.111, s.25C and granted prior to June 1992, if the provider has filed a request for extension, pursuant to 105 CMR 100.756 and 105 CMR 100.551 (E1/2), prior to January 1, 2000. Six (6) projects will be affected by this amendment. The second amendment extends to January 1, 2007, the authorization period for determinations for any convalescent, nursing and rest home projects, if made under M.G.L.c.111,s.25C and granted after June 1992. Approximately 105 projects will be affected by this amendment. The proposed amendment to extend the authorization period for determinations for new construction of nursing facilities from January 1, 2000 to January 1, 2003 was precipitated by the significant number of beds that have left the system in the past eighteen months: 1,338 beds closed in 1999 and 986 have closed during the first half of 2000. Thus, it seems prudent public policy to keep these projects in the pipeline in the event the beds are needed. The proposed amendment to extend the authorization period for determinations for replacement and renovations of nursing facilities from January 1, 2002 to January 1, 2007, reflects the distressed financial situation in the industry for the past three years, resulting in difficulties in securing

capital financing. This extension will allow providers the option of waiting out the present financial situation or abandoning their project. Staff will hold a public hearing on the proposed amendment and return to the Council as soon as possible with the proposed final regulations for Council's adoption."
No Vote/Information Only

INFORMATIONAL BRIEFING ON PROPOSED AMENDMENTS TO REGULATIONS FOR LEAD POISONING PREVENTION AND CONTROL - 105 CMR 460.000:

Mr. Paul Hunter, Director, Childhood Lead Poisoning Prevention Program, accompanied by Mr. Roy Petre, Assistant Director, presented the informational data on proposed amendments to the state's lead regulations. Mr. Hunter noted, "In early 1998, we reconvened the screening committee made up of 25 members including pediatricians, insurers, managed care providers, laboratories, and public health officials. Reflecting the recommendation of the screening advisory committee, the proposed regulations maintain the current annual universal screening at ages one, two, and three years, but replace the fourth-year universal screening with targeted screening of children who reside in the state's 20 communities at highest risk for lead poisoning. The committee based its recommendation on screening data which showed that while great progress had been made in reducing the incidence and prevalence of lead poisoning, too many Massachusetts children are identified with blood lead levels of 20 mcg/dl or greater after age two to make any substantial change in the present screening schedule. We are adopting the American Academy of Pediatrics recommendations for follow up for children with elevated lead levels so that children with blood levels of 10 ug/dl or greater should receive certain follow-up services that hopefully will reduce their exposure or length of exposure. In addition, the proposed regulations will require health care providers practices that analyze blood specimens and laboratories to report the test results electronically within a one-week period."

Mr. Roy Petre added, "The proposed regulations set out training requirements for former lead inspectors or risk assessors who allow their licenses to lapse. If the break has been a year or less, they are required to make up all periodic refresher trainings that are offered. If the license has lapsed longer than that, then they have to take the full training course over. If the break has been more than a year, an abbreviated field apprenticeship must be taken. Another area of proposed regulation incorporates longstanding code enforcement policy. Owners of property in which a child under six resides at the time a code enforcement inspection is performed, and lead violations are found, are required to abate that property whether or not the child continues residence. The reason behind this being that sometimes the owners can try to force the families out following the identification of lead hazards."

No Vote/Information Only

INFORMATIONAL BRIEFING ON AMENDMENT OF HOSPITAL LICENSURE REGULATIONS, 105 CMR 130.000 ET SEQ. TO ALLOW SATELLITE HEALTH FACILITIES TO ACCEPT UNSCHEDULED AMBULANCE TRANSPORT:

Dr. Paul Dreyer, Director, Division of Health Care Quality, accompanied by Attorney Carl Rosenfield, Deputy General Counsel, made the informational briefing to the Council on proposed regulations 105 CMR 130.000.

Staff said, "Current hospital licensure regulations set out the conditions that hospitals must meet to be licensed to provide emergency services. Current ambulance service regulations and emergency medical service protocols contemplate the unscheduled ambulance transport of patients to hospitals that are licensed to provide emergency services. In recent years, as hospitals have closed or downsized, the Department has considered requests from hospital systems to allow the emergency transport of patients to facilities that provide less than the full range of hospital services. The Department has considered and approved these requests via the mechanism of the 'special project approval', a provision in the hospital licensure regulations that allows for the approval of innovative service delivery modalities. Under the aegis of the special project, the Department has approved the satellite emergency facilities at the Burbank campus of the HealthAlliance hospitals and the Southwood campus of Caritas-Norwood. The Department's experience to date has led to the conclusion that the concept of the satellite emergency facility should be embodied in regulation. The Department therefore convened a task force of emergency department physicians and others expert in the provision of emergency medical services to develop regulations that define a satellite emergency facility; that is, a facility less than a full service hospital that nevertheless could accept unscheduled ambulance transport via the 911 system."

Staff continued, "The proposed regulations set out the conditions that a satellite emergency facility (SEF) must meet in order to accept unscheduled emergency transport, and the process that a hospital must follow in developing an SEF in the event that the SEF results from the downsizing of a full service emergency department. The proposed clinical standards include the requirement that physicians staffing the SEF must be board certified or board prepared in emergency medicine as recognized by the American Board of Emergency Medicine (ABEM) or the American Board of Osteopathic Emergency Medicine (ABOEM). Any hospital that develops an SEF as the result of the downsizing of an existing hospital emergency service must comply with an extensive process for notifying the public, holding a public hearing on the new service it proposes to provide, and educating the public about the implications of the change in service." After the public hearing, the proposed regulations with appropriate amendments will return to the Council for promulgation. **NO VOTE/ INFORMATION ONLY**

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The meeting adjourned at 11:05 A.M.

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Howard K. Koh, M.D., M.P.H.

LMH Chairman

MINUTES OF THE PUBLIC HEALTH COUNCIL

MEETING OF JULY 18, 2000

MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH